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## 1 INHALER

This invention relates to dispensers for use with sol containers which contain medicaments for 5 inhalation therapy, are pressurised with liquid propellants, and include a metaring valve through which a series of netered medicament doses can be dispensed.

Inhalation activatable dispensers for use with 10 aerosol container assemblies of the type described above are known, their general purpose being to afford proper co-ordination of the dispensing of a dose of medicament with the inhalation of the patient thereby allowing the maximum proportion of the dose of medicament to be drawn 15 into the patient's brunchial passages. Examples of such dispensers are described in British Patent Specification Nos. 1,269,554, 1,335,378, 1,392,192 and 2,061,116 and United States Potent Hos. 3,455,644, 3,456,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 20 3,732,864, 3,636,949, 3,789,843 and 3,187,748 and German

Patent Ho. 3,040,641. European Petent No. 147028 discloses an inhalation activatable dispenser for use with an aerosol container

in which a latch mechanism releasing wans is pivotally 25 mounted in an air passage between an aerusol outlet valve and a nouthpiece, which latch mechanism cannot be released if force to activate the dispenser is not applied before a patient inhales.

The dispenser generally comprises a housing having a 30 nouthpiece and an air passage therethrough terminating at the mouthpiece, the housing being adapted to receive an serosol container, said dispenser having a support block with a socket adapted to receive the stem of the valve of the serosol container and a through orifice communicating

35 between the socket and the air passage, and latch means having parts novable between an engaged position in which

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ent of the container and the support block toward each other upon the application of a force to bias the container and the support block toward each other is prevented and a release position in which movement of the container and the support block toward each other in response to said force is permitted causing the stem to move to its inner discharge position, the latch means comprising a vane pounted in the housing in the air 10 passageway between the crifice and the nouthpiece for wement toward the mouthpiece under the influence of inhalation through the mouthpiece to release the latch means in which the wans noves toward the nouthpiece from a blocking to a non-blocking position with respect to the 15 passageway in response to inhaling at the mouthpiece and releases the latch means only during the application of said force to bias the container and support block toward each other.

This inhalation device has been received favourably 20 by patients and doctors since it not only overcomes the hand-lung co-ordination problem but it does so at a vary low triggaring flow-rate (approximately 10 litres/minute) essentially silently, and with a very compact design barely larger than a standard inhaler. It is necessary 25 to manually prime the inhalation device with a lever to apply the bias to the container prior to use.

U.S. Patent Bo. 4,648,393 discloses an electricallyoperated metered-done inhaler in which a mechanical valve blocking means is withdrawn by the action of a solenoid 10 nowing in response to the closing of a switch; the switch constitutes an electromechanical breath-actuation means which responds to inhalation by the patient. The disclosed device relies entirely upon mechanical prining of the device by application of force to a spring.

9087/04354 discloses a medical doxing device for the discharge of medicament for inhalation which comprises a

handheld holder for a pedicine container from which sedicine is discharged via a valve into an air channel for inhelation controlled by operation of an activation 5 device. The valve is operationally connected with a control unit arranged on initiation of the activation device to control the discharge valve for intermittent opening and closing repeatedly within an inhelation period. The control unit is an electronically controlled unit which activates an electrically controlled discharge valve.

It is an object of the present invantion to provide an inhalation device for use with a pressurised acrosol container equipped with a metered dose dispensing valve 15 which does not require manual actuation for firing the valve.

Therefore according to the present invention there is provided an inhalation device for use with a 20 pressurised aerosol canister containing a self-propelling sedicament composition equipped with a dispensing valve having a stem movable relative to the canister between a closed position and a dispensing position, the device comprising a bousing for supporting said canister and maintaining the valve stem in a fixed position relative to said housing in communication with a patient port, the device additionally comprising electromechanical means for moving said canister thereby actuating the dispensing valve for administration of medicament.

The invention provides an inhalation device which removes the need for the patient to manually actuate the seronol valve by utilising electromechanical means, e.g., an electric motor or solenoid, to apply the required load for valve actuation to the serosol canister or its associated valve ferrule. The provision of electromechanical means of valve actuation constitutes a

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Alternatively, the electromechanical means may be in

the form of a solemoid which may be used to apply load

directly to the aerosol canister or wie an intermediate 5 linkage to provide mechanical advantage in a similar manner to the linkages associated with an electric motor. After actuation of the valve, the valve must be reset by returning the conister to its original position. The valve may be reset by returning the electromechanical 10 means to its original position and allowing the serosol canister to move under the influence of an internal spring within the valve, which is conventionally incorporated in all commercially available metared dose serosol valves. In one embodiment of the invention the 15 dispenser additionally comprises means for subsequently resetting the valve which may be operated by an electric notor or solemoid to drive the serosol canister back to its rest position. The motor or solenoid may conveniently be the same as that used for valve 20 actuation. The use of such reset means reduces the dependence upon the internal spring within the aerosol valve and accordingly the valve may be provided with an internal spring of refused strength, compared to those conventionally employed, such that it need only be strong 25 enough to return the aerosol valve to the reset position after pressure filling or function testing of the merosol vial during nammfacture. The strength of the valve spring is preferably selected so that a force of no reater than about 15% is required to effect actuation of 30 the device compared with a force of from 18 to 355 for conventional aerosol valves. Reducing the strength of the valve spring reduces the force required to actuate

the valve and, in turn, reduces the power requirements of

35 requirements of the associated battery. Thus, the use of

the notor or colemnia and the power and energy

significant benefit for those patients, generally children, the elderly and infirm, who may experience difficulty in manually firing an earosol valve. A conventional serosol valve generally requires a force of from 18 to 15% to effect actuation. In a preferred embodiment of the invention the electromechanical means is associated with breath detection means such that the aerosol valve is actuated automatically during inhalation by the patient, thereby overcoming any problems associated with potient hand-lung co-ordination.

The electromechanical means actuates the aerosol valve by applying a load either directly or indirectly to the aerosol canister or its associated valve ferrule whilst the valve stem is held stationary. Applying the load to the canister in this vay, rather than to the valve stem, has the important advantage of keeping the support block which houses the spray axit orifice stationary thereby obviating the need to move the southpiece in unison with the support block during actuation to ensure that the medicament is always dispensed to the same area in the mouthpiece and that doeses reproducibility is efficient.

An electric motor may be used to apply the load to
the canister by muserous different arrangements. For
example, the motor may drive through a worm gear attached
to a threaded component which acts directly on the besse
of the cerosol canister. Actuation of the motor in one
direction causes advance of the threaded component moving
the aerosol canister to actuate the valve. In other
embodiments of the invention one or more intermediate
linkages are provided to achieve greater mechanical
advantage. For example, a lever which is driven via a
worm gear, a can or suitable gear train may be utilized
to apply the load to the canister.

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valves having weak valve springs is a significant advantage in the design of pressurised inhalers having electromagnetic valve actuation and reset. The use of 5 valves having weak springs and being reset by an electric motor or solenoid requires the valve stem to be hald in position in the norale block.

Preferred inhalation devices in accordance with the invention additionally comprise means for detecting inspiration through the patient port associated with control manns for actuating the device on detecting of inspiration. Such a breath actuation means may comprise a simple pivoted vane which moves to close an electric switch when the patient inhales through the patient port or may comprise other seams for detection of inhalation, e.g., based upon change in temperature or pressure which provides a signal used to initiate activation of the electronechanical means to activate the valve. Other suitable means for detection of inhalation include flow sensors e.g. those which measure the speed of rotation of a turbine in the air stream.

Smitable inhalation devices are disclosed in our copending British Patent Application of even data entitled
25 "Inhalation Device" and comprise a portable inhalation
device for administration of medicament in the form of
aerosolised fine particles or droplets of liquid or
suspension to the respiratory system of a patient, the
device comprising a housing defining a charber in
30 communication with a patient port in the form of a
mouthpiece or masal adaptor, medicament serosolisation
means for forming an aerosol of medicament in the
chamber, control means to actuate the medicament
aerosolisation means and a sensor which measures the air
35 flow rate during respiration through the patient port and
provides an electrical signal to the control means which

varies continuously with sold flow rate, said electrical signal being used by the control means for one or more of the following functions:

- (i) to calibrate the device such that the medicament aerosolisation means is actuated at a precise, pre-datarained flow rate,
- (ii) to monitor one or more of the following parameters:
- (a) flow rate at different times during respiration,
- (b) rate of change of flow rate during respiration, (c) respired volume during respiration, and activate the nedicament serosolisation means when a 15 pre-determined inspiration parameter is attained.

The electromechanical breath actuated inhalers of the invention aliminate the need for namual actuation or priming of the device and avoid the need for a blocking mechanism to prevent firing of the valve which are required in devices where the mechanism is primed prior to breath actuation. In the devices of the invention, upon detection of the start of inhalation, or the attainment of some inhalation paremeter, the notor or solenoid is emergised and the load immediately applied to the acrosol canistar causing the acrosol valve to fire.

The inhalation device of the invention may also include other electronic control features, e.g., to provide an indication of the number of doses dispensed or 10 remaining, or to control the dosage frequency. For example, the device may include electronic control means such that the aerosol valve cannot be fired for a predetermined period of time after a dose has been dispensed in order to ensure the patient dose not take a further 15 dose before the initial dose has had time to take effect. The control means may also prevent dispensing from the

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Figures 9 and 10 represent side and front sections respectively through an inhalation device in accordance with the invention.

Bach of Figures 1 to 8 illustrate an inhalation device comprising a housing (2) having a patient port (4) in the form of a mouthpiece. The device comprises a nossle block (6) which is first relative to the nouthpiece. A pressurined aerosol vial comprising an extension canister (8) equipped with a valve having a valve stem (10) is enclosed within the housing and arranged such that the valve stem (10) is firmly secured within the norsle block (6). Howement of the servesol canister (8) in the downward direction causes actuation of the valve dispensing medicament through the nossle block (6) into the nouthpiece (4) for inhalation by the petient.

In any of the inhalers shown in Figures 1, 2, 3, 4 and 5 the poter could have associated with it a gearbox.

Referring to Figure 1 the electromechanical means
for noving the aerosol canister (8) to fire the valve
comprises a motor (12) attached to the housing (2) to
prevent rotation which rotates a screw thread (14)
passing through a threaded aparture on actuation lever
(16). Activation of the notor rotates the screw thread
(14) causing the actuation lever (16) to move downwards
thereby moving the serosol canister (8) and firing the
valve (4). Vertical translational motion of the
actuation lever (16) is ensured by two long (17), only
one of which is shown, which engage complimentary
overtical slots (not shown) in the vall of housing (2)
thereby preventing rotation in any plane.

The device additionally comprises a second screw thread (18) passing through a threaded aparture on a valve reset arm (20) extending beneath the valve ferrule. When the motor is actuated to fire the valve the screw (18) is rotated causing downward novement of the reset device if the patient has received the maximum number of dones within a pre-determined period of time in order to prevent patient overdose. In addition, the control neams new also prevent further dispensing from the device when a predetermined number of doses indicated on a label have already been taken, thus preventing "tail off" problems leading to reduced doses of medicanent being dispensed. Since the electromechanical means would only be energised upon demand if so directed by the electronic control means the possibility of valve actuation when not permitted say be completely eliminated by ensuring the canister base and other internal components are inaccessible, thereby preventing unauthorized patient tamporing etc.

The electronic control means may also control the valve resetting to ensure that the valve is reset under motimum conditions. Ideally, the valve should be reset immediately or shortly after valve actuation to ensure 20 the device is set ready for the next use. Such immediate resetting greatly reduces or eliminates the possibility of vapour-lock formation in the valve which can occur if the valve is left in its fired state for a significant length of time or is allowed to reset when 25 the aerosol container is not held in the unright position. In addition, the control means for valve resetting may include a tilt-detection means which provides a warning to the patient to hold the container vertically in order to prevent a vapour-lock occurring if 30 the valve is reset when the serosol canister is tilted and the liquid medicament therein is not in contact with

The invention will now be described with reference to the accompanying drawings in which:

7 Figures 1 to 8 represent schematic diagrams of inhalation devices in accordance with the invention and,

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arn (20) to allow movement of the earceol canister (8).
Rotation of reset arn (20) is similarly prevented by two
interenging lugs/slots (not shown). When the valve is
5 reset the motor is rotated in the opposite direction
causing actuation lever (16) to return to its rest
position and the reset arn (20) is reised with the
aerosol canister (8) upwardly to its rest position.

The device may be actuated by manual pressing of a button (not shown) or by electrical inhalation detection circuitry (not shown). Actuation of the reset cycle may be initiated by namual pressing of a reset buttom, by electrical detection means which detects the cessation of patient inspiration, by a switch actuated on replacement 15 or closing of a muthplece cover or after a preset time delay following actuation of the valve or immediately after the device has fired, or a combination of the above (a.g. preset delay after cessation).

The electrosechanical means for moving the canistar
of the device shown in Figure 2 comprises a motor (22)
attached to the housing (2) to prevent rotation which
drives a screw (24) associated with a combined actuation
driver (26) and reset arm (28). During actuation
rotation of the screw (24) causes the actuation driver
(26) to move downwardly causing corresponding movement of
the serosol canister to fire the valve. Rotation of the
combined actuation driver/reset arm is prevented by lugs
(29) which engage complimentary vertical slots or grooves
in the wall of the bousing. The reset arm (28) moves
with the actuation driver and the valve is reset by
driving the notor in reverse. Actuation of the valve and
reset any be initiated by similar means to those
discussed with referement to Figure 1.

With reference to Figure 3, the electromechanical neans for moving the serosol canister comprises a motor (30) attached to the housing (2) to prevent rotation 5 which drives a screw (32) associated with a combined actuation driver (34) and reset arm (36) Which are positioned either side of the valve ferrule (38) and are prevented from rotating with the screw. When the motor is activated to rotate the screw (32) the actuation 10 driver (14) and reset arm (36) move downwardly causing povement of the serosol canister (8) to fire the valve. The motor is then driven in reverse, returning the actuation driver and reset arm to the rest position causing upward movement of the canister (8) to reset the 15 valve. Alternatively, the reset arm (36) may be eliminated, both valve actuation and reset being performed by driver (34). Actuation of the firing and resetting cycles of the valve may be arranged as discussed with reference to Pigure 1.

Referring to Figure 4, the electromechanical means for poving the canister is similar to that shown in Figure 3 and comprises a mother (40), screw (42), actuation driver (44) acting on the valve ferrule (48) and a reset lever (46) which is connected to the 25 actuation driver (44) at pivot (47). Two lugs (45) are provided to prevent rotation of the actuation driver (44) as described above for the device shown in Figure 1. The valve firing and resetting cycles operate as described with reference to Figure 3.

The electromechanical means for moving the aerosol 30 canister in the device shown in Figure 5 comprises a motor (50) having a shaft (52) which is attached to a cam (54). The surface of the cam (54) acts on actuation driver (56) such that when the cam is rotated the 35 actuation driver is caused to move downwardly, in turn causing down povement of the aerosol canister (8) to fire

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the device housing at (81). When the device is actuated by energiaing the solemoid the plunger (72) moves downwardly pulling the actuation lever (74) which in turn 5 causes downward movement of the serosol canister (8) firing the valve. The two pivot points (77, 81) are chosen so that the reset arm (78) moves downwardly during the actuation cycle allowing free movement of the serosol canister and when the solemoid is de-energised the 10 plunger returns to its rest position causing upward novement of the actuation lever (74) and reset arm (78) moving the serosol canister (8) to its rest position thereby resetting the valve. The initiation of the valve firing cycle may be conducted as described with reference 15 to the device illustrated in Figure 1.

Referring to Figure 8 the electromechanical means for moving the aerosol canister (8) comprises a solemoid (80), plunger (82) which is commected to cam (84) by a pivoted linkage (86). The can (84) rotates about (85) to act on an actuation driver (88) which is positioned at the base of the aerosol canister (8). When the solemoid is energised, the plunger moves upwardly and the pivoted linkage (86) causes the can (84) to rotate pushing the actuation driver (88) downwardly causing movement of the 25 serosol canister (8) to fire the valve. When the solenoid is de-energised and the plunger returns to its rest position causing rotation of the cam to its rest position the aerosol canister (8) and the actuation driver (88) are moved upwardly under the influence of the 30 internal spring of the aerosol valve.

Figure 9 shows an imbaler (100) with a hinged nonthpiece cover (102) which can be opened to reveal a patient port in the form of a routhpiece (104). The nouthpiece has attached to it a norsle block (106) and 35 the mouthpiece/morsle block are removable for cleaning DUITDOSES.

the valve. Stop (57) on the cap and stop (59) on the actuation driver are provided to halt rotation of the came when the required povement of the serosol canister has been completed. Alternatively, a stepper potor could be used, thereby possibly obviating the need for a separate de-energising switch. The stops may act as a switch to de-energise the motor. The valve reset is achieved by driving the notor in roverse and either noving the 10 canister upwards or allowing the serosol canister to move unwardly under the influence of the internal spring of the serosol valve.

Referring to Figure 6 the electromechanical means for moving the serosol canister (8) commrises a solenoid 15 (60) and a plunger (62) connected to a combined actuation driver (64) and reset arm (66) which act on either mide of the valve ferrule (67). When the solenoid is energised the plunger noves downwardly causing downward movement of the actuation driver, valve reset arm and 20 aerosol canister causing the valve to fire. The solenoid is do-energised and the plunger returns to its rest position under the influence of the solenoid return spring causing upward powement of the actuation driver, valve reset are and aerosol canister to its rest 25 position. Alternatively, the reset arm (66) may be eliminated, both valve actuation and reset being performed by driver (64). The firing and reset cycles of the valve may be initiated in the manner described with reference to the device illustrated in Pigure 1.

Referring to Figure 7, the electromechanical means for moving the aerosol canister (8) comprises a solenoid (70) having a plunger (72) connected to an actuation arm (74) at pivot (75). Actuation arm (74) pivots about (77) to act on the base of the aerosol canister (8) thereby generating mechanical advantage. A reset arm (78) is connected to end (76) of the plunger at pivot (79) and to

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Inserted into the nossle block is the valve ston (108) of a motered dose inhalar (110). The metared dose inhaler will be referred to as an MDI. The valve stem is vented from moving down with respect to the nozzle block by a small projection (112) formed as part of the nossle block. However, there is sufficient space (114) in the notale block to allow the remaining parts of the valve (116) to travel downwards during the action of 'firing' the MDI.

The holes (122) in the rear of the device serve as air inlets when the patient inhales on the mouthpiece. The battery (124) can be accessed through a cover (126) in the back of the device.

Most of the electronic con ents of the device are on a circuit board (128), this could take the form of a printed circuit board or, to save space, an ASIC for xample (i.e. an application specific integrated circuit).

Figure 10 shows a front section of the firing echanism in more detail. The cam (130) takes the form of a short cylindrical block mounted eccentrically ontothe output spindle (132) of a reduction gearbox (134). The can is nounted within a housing (136) which is free 25 to move up and down with respect to the MDI. The can and housing are preferably made from similar materials to

A d.c. noter (138), which could be continuous or of the 'stepper' type, is mounted onto the gearbox so that 30 the notor output drives the gears (not shown). The gears are arranged such that the angular velocity of the motor (typically around 13000 rpm) is reduced to give one revolution in approximately 0.2 to 0.5 seconds. Also attached to the gearbox is a nicro-switch (140), with its actnator arm (142) resting on the top of the housing

The whole of the firing mechanism is ettached to the body of the device (144) by four tension springs (146 to 149) which are attached at one end to a cross-member 5 (150) which bears down on the gearbox and at the other end to the device body.

The operation of the device will now be described. The patient must first shake the device to mix the contents of the serosol can and must ensure that the 10 mouthpieca cover is open and the air intakes are clear.

The patient inhales on the mouthpiece, setting up a flow of air into the intakes (122) and through the empty region (152) of the inhalar. The air travels through channels in the nozzle block to either side of the spray 15 outlet and thereafter out through the mouthplace. (The nozzle block (106) forms a sufficiently good seal with the main body of the device that the preferential path for the air is from the intakes to the mouthpiece).

Whilst still inhaling, the patient must press a 20 switch (not shown) to operate the electro-mechanical firing mechanism. When the switch is depressed the motor is made to turn until the cam has made one complete revolution. As the can turns, it presses downwards on the housing (136) which in turn presses down on the base 25 of the aerosol can. Since the valve stem cannot move with respect to the nozzle block, which is attached to the body of the device, the net result is that the valve stem is pushed up into the serosol can thereby firing the MDI and releasing medicament in the normal way.

When the can returns to the top of its travel the housing contacts the actuator (142) of the micro-switch (140), sending a signal to the electronics to stop the notor.

The diameter of the can and the point at which it is 35 mounted, are arranged such that at the bottom of its travel the cam has caused the valve to be compressed by

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## CLAIMS

- 1. An inhalation device for use with a pressurised serosol canister containing a self-propelling medican 5 composition equipped with a dispensing valve having a stem movable relative to the canister between a closed position and a dispensing position, the device comprising a bousing for supporting said canister and maintaining the valve stem in a fixed position relative 10 to said housing in communication with a patient port, the device additionally comprising electromechanical means for noving said canister thereby actuating the dispensing valve for administration of medicament.
- 2. An inhalation device as claimed in Claim 1 in which 15 the dispensing valve is a notered dose dispensing valve. 1. An inhalation device as claimed in Claim 1 or Claim 2 in which the electromechanical means for moving the serosol canister comprises an electric motor or solenoid connected by a driver arrangement to an actuation driver 20 which acts on the serosol canister or valve ferrole to move the serosol canister when the electric motor or solenoid is energised.
  - 4. A device as claimed in Claim 3 in which the driver arrangement comprises a screw.
- 25 5. A device as claimed in Claim 3 in which the driver arrangement comprises a cam-
- A device as claimed in any preceding Claim which additionally comprises a reset member which acts on the serosol canister or valve ferrule, the reset member being 30 driven by an electric motor or solenoid or solenoid spring to return the aerosol canister to a reset position closing the dispensing valve.
- 7. A device as claimed in Claim 6 in which the electric notor or solenoid or solenoid spring driving the reset 35 member is the electric motor or solemoid or solemoid

spring driving the actuation driver.

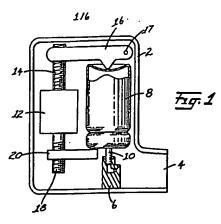
more than the minimum amount necessary to properly fire the MDI. In case the cam is arranged such that the valve compression would exceed the maximum permitted travel, 5 the whole of the firing mechanism can lift, against the action of the four springs, to ensure that the can is always able to make a full rotation without stalling. Thus, the strength of the springs must be arranged so that, when acting in unison, they are sufficiently strong 10 to allow the valve to compress normally without extending, but sufficiently weak as to allow the nechanism to lift if the valve 'bottoms out'.

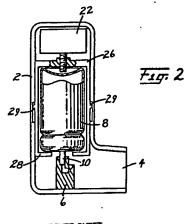
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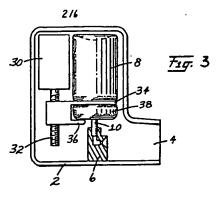
In a preferred variation of this embodiment the device would be made breath activated by incorporating a 15 suitable flow sensor into the space (152). In this case the patient would press a button to turn the electronics on, or a switch could be incorporated in the nouthplace cover and the electro-mechanical firing mechanism would then be operated automatically as soon as the appropriate 20 triggering flow rate or inhalation parameter was detected. Suitable breath sensors are disclosed in the prior art referred to herein and in our co-pending British Patent Application No. 9023282.8 and the PCT Application of even date based thereon, the disclosures 25 of which are incorporated herein by reference.

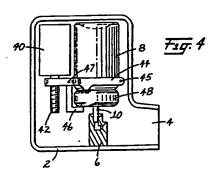
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- 8. A device as claimed in Claim 6 or Claim 7 comprising control means to actuate the valve reset member after firing the valve.
- 5 9. A device on claimed in Claims 6 to 8 which additionally comprises indicating means to prevent valve reset if the canister is not substantially vertical or to warn the patient to hold the canister in a substantially vertical position.
- 10 10. A device as claimed in any one of Claims 6 to 9 in which the dispensing valve comprises a spring bissing the valve stem to the closed position, the strength of the spring being selected so that a force of no greater than 15W is required to effect actuation of the device.
- 15 11. A device as claimed in any preceding Claim which additionally comprises means for detecting patient inspiration through the patient port and control near for actuating the electronechanical means for noving the earosol canister in response to detection of patient
- 20 inspiration. 12. A device as claimed in any preceding Claim which additionally comprises control means to control the dosage frequency by preventing actuation of the electromechanical means for a pre-determined period of
- 25 time after dispensing a dose or a number of doses of nedicament.
  - 1). A device as claimed in any preceding Claim which additionally comprises control means to prevent actuation of the electromechanical means after a predstarmined
- 30 number of doses of medicament have been dispensed from the device.
  - 14. An aerosol device as claimed in any preceding Claim containing said pressurised aerosol canister equipped with a dispensing walve.
- 35 15. A method of administering a medicament using an serosol device as claimed in Claim 14.









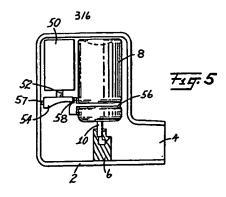
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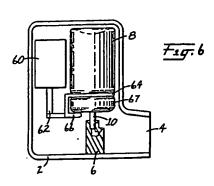
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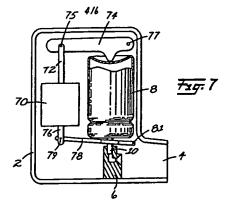
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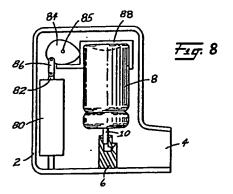
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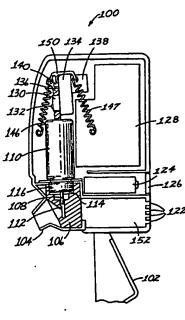


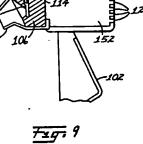


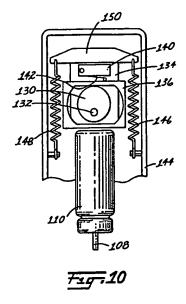




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